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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/609,053

06/27/2003

Richard A. Gambale

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/609,053	Applicant(s) GAMBALE ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 17,18 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16,19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 20-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are directed to another species of the invention, i.e. tissue engagement mechanism with free distal ends.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The restriction requirement regarding claims 16 and 19, as set forth in the Office action mailed on 10/25/06, has been reconsidered in view of the amendment to the claims. Now that these dependent claims are no longer in the form of a distinct species but rather the limitations are part of the originally presented species, these claims have been rejoined.

Specification

The new abstract of the disclosure submitted 4/26/07 does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3763

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segal et al (USPubN 2003/0100886) in view of Ham et al (USPN 5,456,667) or Khosravi (USPN 5,415,637). Segal discloses a method for treating ischemia that includes providing a catheter having a proximal end and a distal end and a radially extendible tissue engagement mechanism, navigating the catheter so that the distal end is adjacent the myocardium, causing the mechanism to extend into engagement with the myocardium and delivering a therapeutic agent while maintaining the tissue engagement mechanism in its extended position. See paragraphs 0062+ and figures 11+.

Segal meets the claim limitations as described above but fails to include the radially extendible tissue engagement mechanism include a plurality of resilient members configured to be selectively engages so that the resilient members extend radially outward from a longitudinal axis where the member lie parallel to the axis when unloaded and bow outwardly under a compressive load. However, both Ham and Khosravi each disclose such a tissue engagement mechanism.

At the time of the invention, it would have been obvious to one skilled in the art to incorporate the tissue engagement mechanism of either Ham or Khosravi into the invention of Segal. One skilled in the art would understand and it is commonly knowledge in the art that the tissue engagement mechanisms of both Ham and Khosravi allow for blood flow while the procedure is taking place. This allows for added safety to the patient while undergoing the

Art Unit: 3763

procedure. One skilled in the art would have been motivated by the enhanced safety of the mechanism.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al (USPN 6,602,241) in view of Ham et al (USPN 5,456,667) or Khosravi (USPN 5,415,637). Makower discloses a method for treating ischemia that includes providing a catheter having a proximal end and a distal end and a radially extendible tissue engagement mechanism, navigating the catheter so that the distal end is adjacent the myocardium, causing the mechanism to extend into engagement with the myocardium and advancing a tissue implant while maintaining the tissue engagement mechanism in its extended position.

Makower meets the claim limitations as described above but fails to include the radially extendible tissue engagement mechanism include a plurality of resilient members configured to be selectively engages so that the resilient members extend radially outward from a longitudinal axis where the member lie parallel to the axis when unloaded and bow outwardly under a compressive load. However, both Ham and Khosravi each disclose such a tissue engagement mechanism.

At the time of the invention, it would have been obvious to one skilled in the art to incorporate the tissue engagement mechanism of either Ham or Khosravi into the invention of Makower. One skilled in the art would understand and it is commonly knowledge in the art that the tissue engagement mechanisms of both Ham and Khosravi allow for blood flow while the procedure is taking place. This allows for added safety to the patient while undergoing the

Art Unit: 3763

procedure. One skilled in the art would have been motivated by the enhanced safety of the mechanism.

Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower in view of Ham or Khosravi; or Segal in view of Ham or Khosravi as applied to claim 12 above in further view of Higgins et al (USPN 5,275,597). Makower in view of Ham or Khosravi; or Segal in view of Ham or Khosravi meet the claim limitations as described above but both rejections fail to include detecting thermal data of the tissue.

However, Higgins discloses an intravascular procedure that includes the detection of thermal data of a vessel wall.

At the time of the invention, it would have been obvious for one skilled in the art to incorporate the thermal detection as taught by Higgins into the inventions of Makower in view of Ham or Khosravi; or Segal in view of Ham or Khosravi. The motivation for the incorporation would have been that temperature detection is well known in the art and is incorporated into many medical devices to further enhance the safety of the device and procedure to the patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3763

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine S. Williams/

Application/Control Number: 10/609,053

Page 7

Art Unit: 3763

Catherine S. Williams

Primary Examiner, Art Unit 3763

July 13, 2007